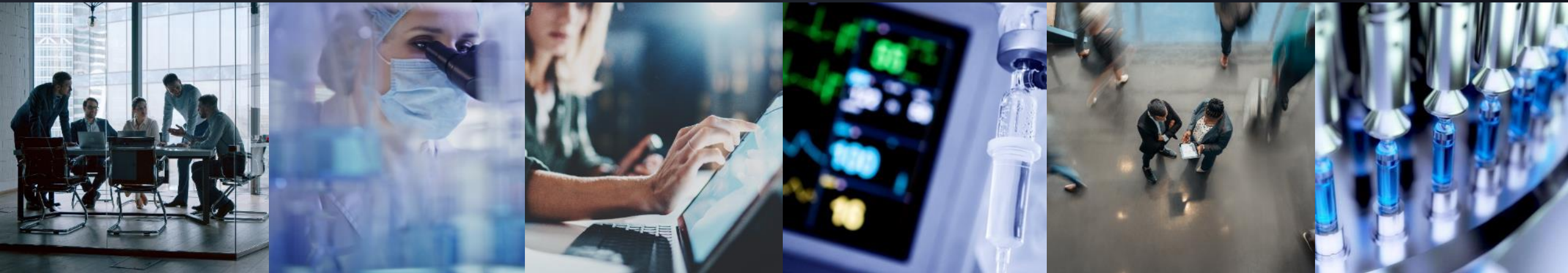


# TRACKWISE USER FORUM

**BRIAN BRZEZINSKI – PRODUCT MANAGER**

November 28, 2023



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# AGENDA

## 1. Introduction to TrackWise User Forum

## 2. TrackWise in 2023

Product Overview & Operations

## 3. ICYMI (In Case You Missed It)

TrackWise 10.8 and other recent releases

## 4. FDA EMDR Gateway Updates

## 5. Preview TrackWise Spring 24

## 6. Lightning Round on New Features & Improvements

Tell us what features are important for your business

# HONEYWELL LIFE SCIENCES TEAM



**Brian Brzezinski**  
Product Manager



**Jason Halpern**  
Director, Product  
Management



**Laura Wirpsza**  
Customer Experience  
Leader



**Zillery Fortner**  
Product Advisor,  
QA/RA

# USER FORUM OVERVIEW



## INFLUENCE

Influence what Honeywell Connected Life Science creates and how it **solves your key business problems**



## PARTNERSHIP

Establish a **collaborative dialogue** between key decision-makers & product owners

**Co-development opportunities** that accelerate your strategic vision or become an **early adopter** of the next leading technology



## TRANSPARENCY

View new products or enhancements that are coming in the **next set of annual releases**

**Thank you for partnering with us  
and being part of our continuous improvement**

# WEBINAR GUIDELINES

- Please raise your hand to add a comment/or ask a question:
- When asking a question please introduce yourself:
  - Name, Company, Role

# TRACKWISE IN 2023

# PRODUCT PRIORITIES



Deliver **User Satisfaction** with intuitive & performance solutions



Build **innovative** features to improve **User Efficiency**



Enable adoption with implementation & upgrade **Accelerators**






Address **customer concerns** through maintenance & deeper engagement





# RELEASES

	Feature	Maintenance
 <b>Content</b>	<ul style="list-style-type: none"> <li>• Major / Minor Version</li> <li>• Enhancements</li> <li>• Validation Package</li> <li>• Supported for 3yrs from release (5yrs extend)</li> </ul>	<ul style="list-style-type: none"> <li>• Service / Patch (A.B.C.D)</li> <li>• No Validation Impact</li> <li>• Commits to main codebase &amp; specific builds</li> <li>• Support based on feature</li> </ul>
 <b>Release Schedule</b>	<ul style="list-style-type: none"> <li>• “Seasonal” (Spring   Summer   Winter)</li> <li>• Spring Tech Updates</li> <li>• Winter Regulatory</li> </ul>	<ul style="list-style-type: none"> <li>• Approx. monthly</li> <li>• Ad-hoc when required</li> </ul>
 <b>Dedicated Teams</b>	<p>Teams focused on scheduled roadmap work</p> <ul style="list-style-type: none"> <li>• Tech Writers</li> <li>• Validation Experts</li> </ul>	<p>“Sustained Engineering” dedicated to defects impacting customers in their version</p>

# ROADMAP DRIVERS



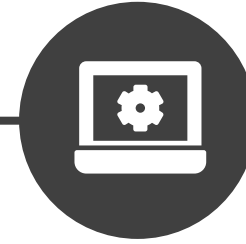
## INDUSTRY

- Regulatory Rules
- Gateway/Submission Changes
- Winter Release Target



## CUSTOMERS

- Enhancement Requests
- Group Feedback Sessions
- R&D Engagements



## TECHNOLOGY

- System Requirement Updates
- Dependency Requirements
- Enhancement Requests
- Spring Release Target

**ICYMI (IN CASE YOU MISSED IT)**

**RECENT RELEASE  
HIGHLIGHTS**

# TRACKWISE INNOVATIONS

## Recent TrackWise 10 Features



### Intelligent Forms

Improve the user experience with just the proper form layout



### Privacy Enhancements

Balance user and data privacy with controls around Data, Activity and Reports



### Reporting Improvements

Providing more control over reports while simplifying installation footprint



### QualityWise.AI Insights

Gain powerful insights through AI-based correlations



### Usability Features

Increase efficiency with usability enhancements



### Easier Upgrades

Opt-in features and simpler requirements make TrackWise easier to take

# INTELLIGENT FORMS

TrackWise 10 intelligently displays relevant parts of a form, improving the efficiency of data entry, clarity of approvals, and effort required to manage system changes.

- Simplified data entry for infrequent users
- Clearly recognize data being approved
- Fewer configuration elements to validate

The screenshot shows a web form titled "Issue Information". It contains the following fields and options:

- Short Desc:** A text input field containing "Supplier notified adulterated ingredient - red11".
- Issue Type:** A dropdown menu with "Deviation" selected.
- Affected Area:** A multi-select dropdown menu with "Product", "Material", and "Process" visible. Below it, "Selected Values: Product, Process" is displayed.
- Issue Source:** A group of radio buttons with "Vendor" selected. Other options include Employee, Servicer, Distributor, Consumer, and Other. A "Clear Selection" link is below.
- Supplier Name:** A text input field containing "Qualified Suppliers, Inc".
- Supplier Address:** A text input field containing "44 Corporate Drive".

# AI INSIGHTS

Announcing the availability of AI for TrackWise  
QualityWise.ai Insights as a hybrid solution for TrackWise customer



Utilize AI to recognize trends across similar records and related records



Identify recurring events and automate decisions



Leverage the historical data in TrackWise for proactive quality

**TrackWise Insights**

Initialized on 11-Nov-2020 09:48PM  
Last Update Date on 13-Sep-2019 07:08PM

**Summary**  
The following records were found to contain similar characteristics: here 92% of records contain Deviation Sub-Type = Component (Last Modified: Nov 1, 2020 to Nov 3, 2020)

**Insights**

PR	Project	Short Desc.	Product Name (Dev)	Date of Status	Weight
3012	Deviation	Raw material out of spec during receiving	Raw Material 123	03-Nov-2020	0.565
3013	Deviation	QC Inspection Issue	Finished Good 1122	30-Oct-2020	0.53
3015	Deviation	Raw material out of spec during receiving	Raw Material 123	26-Oct-2020	0.23
3016	Deviation	Raw material out of spec during receiving	Raw Material 123	26-Oct-2020	0.12

Rows per page: 10 | 1-5 of 5 | < >

# IMPROVED USABILITY



## Familiarity

- Horizontal Desktop
- Query Refresh Events
- Inline Reporting



## Efficiency

- Collapsible Form Sections
- Favorite Column Order
- MS Edge Browser

TrackWise 10 (Demo)

Systems Administrator

PR ID ▾ Enter search value 🔍

Views +

Scopes & Queries

Scopes

- All Projects x ▾

Queries

- All States x ▾

Run

Save as View

Scope: All Projects

All States » 2272 Results [Edit](#)

50 ▾ Results per Page - last updated just now ↻

Actions ▾ ⚙️

PR	Date Opened	State	Short Desc.	Originator	Opened Date	Assigned To	Date Due	End Date of Use	Date Created
1001	06/15/2018 02:28 PM	Closed - Done	Sed vel enim sit amet nunc viverra dapibus.	Systems Administrator	07/17/2017 05:06 AM				06/15/2018 02:28 PM
1002	06/15/2018 02:28 PM	Pending Approval	Pellentesque at nulla.	Systems Administrator	09/07/2018 01:29 PM	Scott MacDonald	12/06/2018		06/15/2018 02:28 PM
1003	06/15/2018 02:28 PM	Closed - Done	Morbi sem mauris, laoreet ut, rhoncus aliquet, pulvinar sed, nisl.	Systems Administrator	06/29/2017 12:30 AM				06/15/2018 02:28 PM

Showing 1 to 50 of 2272

Previous 1 2 3 4 5 ... 46 Next

# REPORTING ENHANCEMENTS

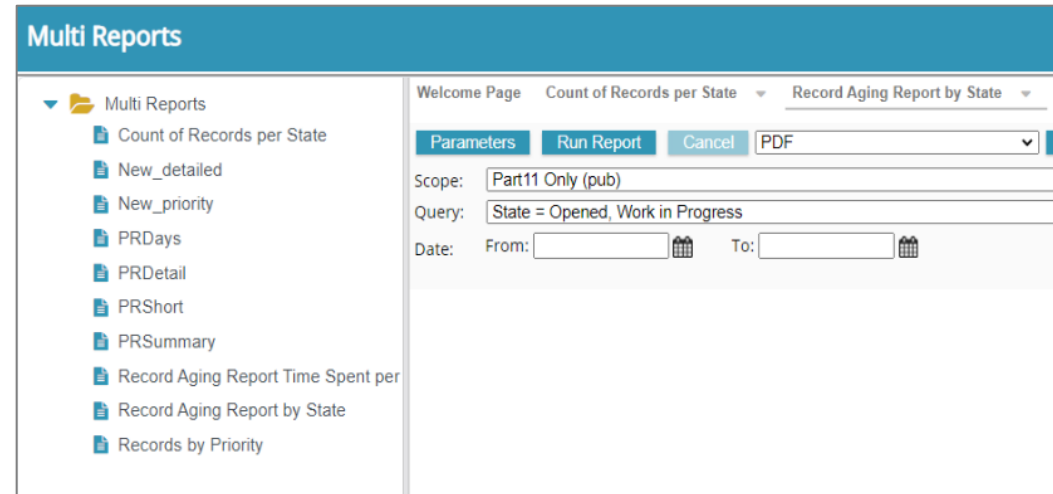
Simpler Installations and More Controls

## Accelerating Setup

- Faster, Easier installation for customers without QualityView license
- Manage QualityView separately for customers with a license
- Cloud-friendly with fewer resources required

## User Experience

- Minimal User Impact (Dedicated Button, Minimal Menu Changes)
- Multi-Reports not impacted by Chrome/Edge change
- Report class by user role grants specific access





# FILE ATTACHMENTS

Manage File Attachments faster with contemporary controls

## User Experience

- Improve user efficiency & comfort with Drag & Drop and the ability to upload multiple files
- Intuitive file management controls
- File-Extension safe list ensures only permitted file types are allowed

## File History

- Richer attachment history allows for accessing complete file contents
- Improve confidence in system compliance with traceability to full audit trail

**File Attachment**  
PR# 1007

Attachments & Tra

File Attachment

QualityDocTest.docx

View Manage

Drop files to attach or click and browse.

File Name (View Full Path)

[QualityDocTest.docx](#)

[Corporate Document 1007.pdf](#)

**File Attachment** ? x

File Revision History For QualityDocTest.docx

Sequence No	File Name	Size
2	<a href="#">QualityDocTest.docx</a>	15 KB
1	<a href="#">QualityDocTest.docx</a>	15 KB

OK

# **E-REPORTING EMDR ENHANCEMENTS**

# EMDR ENHANCEMENTS

Improved submission management & gateway compliance



## FDA GATEWAY

E-Reporting tool updated for latest FDA changes

- Updated Fields & other 3500A Form Changes
- Mandatory by March 31<sup>st</sup>
- Release Candidate will be available



## VALIDATION RULES

Additional Rules to Validate EMDR data ensures complete & timely reporting of adverse events

- Mandatory Fields
- Data Formatting
- Product / Device Code lookup from FDA worksheets



## SUBMISSION MANAGEMENT

Track acknowledgement messages as they are received

- Identify missing ACKs quickly & easily
- Generate reports/exports to resolve issues efficiently
- Requires additional mapping & AS2 Message Id

# EMDR GATEWAY CHANGES

FDA Gateway being updated to align with latest Medwatch 3500A – Mandatory for all E-Reporting customers

## What's Involved?

- Install / Upgrade Utilities
- TrackWise Configuration
  - Data Fields
  - Selection Values
  - Permissions
  - Layouts
- Configuration Mapping
- Crystal Reports

## Key Dates

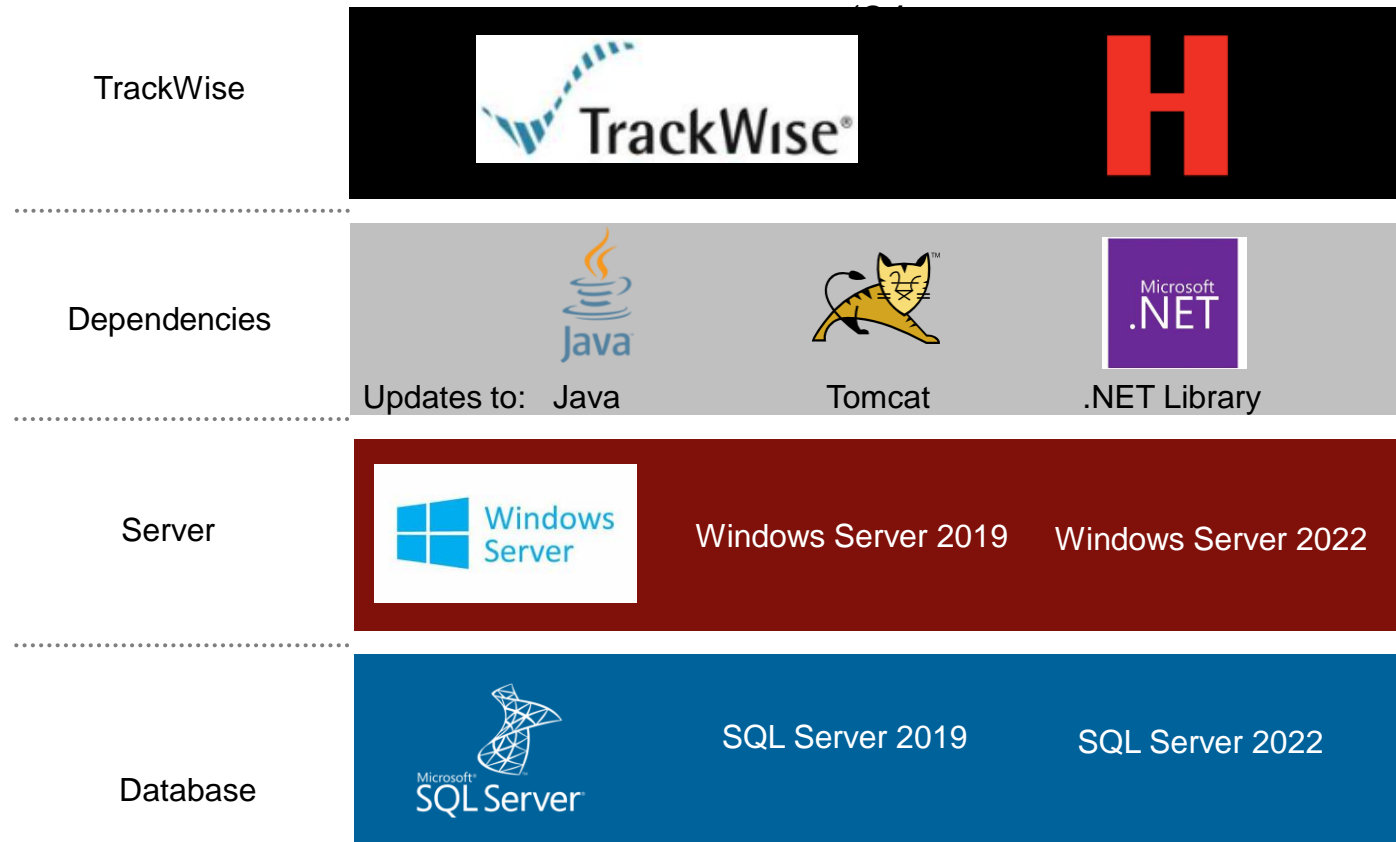
- **December 1<sup>st</sup>**
  - FDA Test System Online
- **December 20<sup>th</sup>**
  - E-Reporting 2.13 Release Candidate
- **January 17<sup>th</sup>**
  - E-Reporting 2.13 General Availability
- **March 31<sup>st</sup>**
  - Mandatory Submissions in Production

# PREVIEW TRACKWISE SPRING '24

# SPRING '24 PREVIEW

What's coming in TrackWise 10.9

## Changes expected in Spring



Unchanged  
(Planned for Spring '25)

ORACLE

Crystal Reports

QualityView

# TRACKWISE TECH STACK

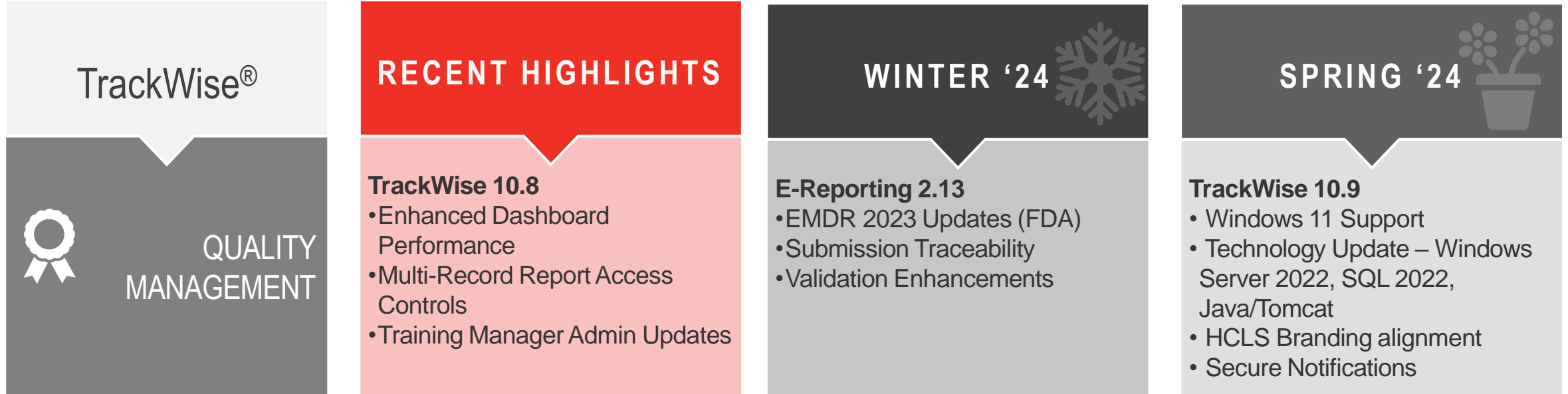
Changes across TrackWise versions

TW Version	System Requirement	End of Mainstream	End of Extended	Notes
9.0	Windows Server 2012	Oct 2018	Oct 2023	
9.1	SQL Server 2012	July 2017	July 2022	Beyond extended support, at risk for infrastructure
9.2	Oracle 12g	Nov 2020	Mar 2022	Upgrade low user impact
9.3	Windows Server 2016	Jan 2022	Jan 2027	
9.4	SQL Server 2016	July 2021	July 2026	Already in extended support (\$\$)
9.5	Oracle 12g/19c			TW is beyond 3yr window
10.0	Windows Server 2016	Jan 2022	Jan 2027	
10.1	SQL Server 2016	July 2021	July 2026	Already in extended support (\$\$)
10.2	Oracle 19c	April 2024	April 2027	TW is nearing 3yr window
10.3	Windows Server 2019	Jan 2024	Jan 2029	
10.4	SQL Server 2019	Feb 2025	Jan 2030	Nearing extended support (\$\$)
10.5	Oracle 19c			
10.6				
10.7				
10.8				
10.9	Windows Server 2022	Oct 2026	Oct 2031	
TBD	SQL Server 2022	Jan 2028	Jan 2033	
	Oracle 19c (23c TBD)			

# **LIGHTNING ROUND ON NEW FEATURES & IMPROVEMENTS**



# TRACKWISE ROADMAP SUMMARY



TrackWise®



QUALITY  
MANAGEMENT

## RECENT HIGHLIGHTS

### TrackWise 10.8

- Enhanced Dashboard Performance
- Multi-Record Report Access Controls
- Training Manager Admin Updates

## WINTER '24



### E-Reporting 2.13

- EMDR 2023 Updates (FDA)
- Submission Traceability
- Validation Enhancements

## SPRING '24




### TrackWise 10.9

- Windows 11 Support
- Technology Update – Windows Server 2022, SQL 2022, Java/Tomcat
- HCLS Branding alignment
- Secure Notifications

# TRACKWISE ROADMAP SUMMARY

TrackWise®



QUALITY  
MANAGEMENT

SUMMER '24

**TrackWise 10.10**

- Batch-Edit Enhancements
- Field Validation & Formatting
- Platform Enhancements

WINTER '24

**TrackWise 10.11**

- E-Reporting Updates
- Webservices Enhancements

FUTURE

- Tech Stack (Oracle 23c / Crystal)
- Query Manager Refresh
- Grid Additional Field Types
- Form & UX Enhancements
- Utility/E-Rpt Performance
- EUDAMED / MIR 7.3

# UPCOMING INITIATIVES

Rank upcoming topics by interest

- 1. Query Manager Refresh** – Powerful searching capabilities and updated Look & Feel
- 2. Upgrade Assistant** – Gap analysis tools to help adopt new versions faster
- 3. Admin/Cloud Management** – Tools to help deploy in cloud environments (scaling resources, server-specific administration)
- 4. UX Updates** – Visual changes to enhance user efficiency (Pinned Fields, Grid Refresh, Instance Notifications)
- 5. Regulatory Reporting** – Decision Trees & “One Path To Many” tools to streamline submissions to various regulatory bodies

# WRAP UP

<https://www.research.net/r/TW-UF-Nov23>

# NEW OFFERINGS

New offerings and Upcoming Events

## Life Sciences Application Suite (LSAS)

Annual Product  
Quality Review  
offering available  
as a compliment  
to existing  
TrackWise  
capability

## EMDR Configuration

Be ready for latest  
EMDR changes  
with  
configuration  
support to  
expedite gap  
analysis and  
deployment of  
changes

## Upgrade Services

Avoid extended  
support fees by  
upgrading to the  
latest versions  
in Spring '24

## Digital Acceleration Center

New offering to  
assist in  
evaluating  
digital  
transformations

# TUG AMERICAS

Exclusive events for TrackWise  
and TrackWise Digital customers

**San Francisco**  
February 1, 2024

**Philadelphia**  
February 29, 2024





# **PROGRAM INTRO: DIGITAL ACCELERATION CENTER**

# DIGITAL ACCELERATION CENTER



Leverage  
Existing TrackWise  
Investment  
for  
Faster and Lower  
Cost Conversions

- **Minimize change and business impact** by migrating current quality processes and procedures to TrackWise Digital
- **Uses their current investment** to create processes that work for them...*Optimize where needed via QPAs*
- **Limits disruption to the business users**; processes remain the same, just updated UX
  - Less training
  - Continue using SOPs
  - Leverage validation documentation
- **Quicker process**; Limited Design Phase and reusable requirements



# THANK YOU.



Tell us how we did!

<https://www.research.net/r/TW-UF-Nov23>

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